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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/851,230	05/08/2001	John Hamilton	111590-121 (US2)	4015
28089	7590	11/30/2004	EXAMINER	
WILMER CUTLER PICKERING HALE AND DORR LLP 399 PARK AVENUE NEW YORK, NY 10022			BELYAVSKYI, MICHAEL A	
			ART UNIT	PAPER NUMBER
			1644	

DATE MAILED: 11/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/851,230	HAMILTON ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Michail A Belyavskyi	1644	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 November 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 14-27 and 29-34 is/are pending in the application.
- 4a) Of the above claim(s) 14-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 29-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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RESPONSE TO APPLICANT'S AMENDMENT

1. Applicant's amendment, filed 11/08/04 is acknowledged.

Claims 14-27 and 29-34 are pending.

2. Claims 14-27 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b) as being drawn to nonelected inventions.

*Claims 29-34 are under consideration in the instant application.*

In view of the amendment, filed 11/08/04 the following rejections remain

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

*(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.*

*(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 37(c) of this title before the invention thereof by the applicant for patent.*

4. Claims 29-33 stand rejected under 35 U.S.C. 102(a) as being anticipated by WO 00/09561 as evidenced by newly cited Bost et al. (Immunol. Invest. 1988; 17:577-586) and Bendayan (J. Histochem. Cytochem. 1995; 43: 881-886) for the same reasons set forth in the previous Office Action, mailed 05/06/04.

Applicant's arguments, filed 9/25/00 (Paper No. 10), have been fully considered, but have not been found convincing.

Applicant asserts that : (i) antibodies against GM-SCF taught by WO'561 are not specific because they reactive with multiple cytokines ; (ii) WO'561 does not teach the use of antibodies to ameliorate inflammatory conditions.

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Contary to Applicant's assertion, it is the Examiner position, that the antibody taught by WO'561 is specific for GM-CFS.

The fact that an antibody "cross-reacts", i.e. binds to more than one protein sequence, does not mean that the antibody does not "specifically react" with both proteins. Evidentiary reference Bost et al. (Immunol. Invest. 1988; 17:577-586) disclose antibodies which "cross-react" with IL-2 and HIV envelope protein, but establish that the binding of each protein is due to the presence of a homologous sequence in each protein in which 4 of 6 residues were identical (see entire document, but especially the Abstract and Discussion). Antibodies which bound either the HIV or IL-2 derived sequence did not cross-react with irrelevant peptides (e.g., Results, page 579). Similarly, Bendayan (J. Histochem. Cytochem. 1995; 43: 881-886) characterizes the specific reactivity of a monoclonal antibody produced to human proinsulin, and shows that although the antibody is highly specific, it is nevertheless able to bind to not only human proinsulin, but to proinsulin from other species and even a distinct protein, glucagons, based upon conservation of an Arg-Arg dipeptide sequence in each of these molecules (see entire document). Bendayan concludes that "an antibody directed against such a sequence, although still yielding specific labeling, could reveal different molecules not related to the original antigen" (page 886, last paragraph). Consequently, it was well known in the art that antibody binding of distinct proteins was indeed specific.

With regards to Applicant's comments that WO'561 does not teach the use of antibody to ameliorate inflammatory conditions. Applicant's attention is respectively drawn to overlapping pages 6-7 of WO'561. It is explicitly disclosed that antibodies of the invention are used to treat disease associated with chronic inflammation.

Claims 30 and 33 are included because the claimed functional limitation would be inherent properties of the referenced antibodies against GM-CSF, because the claimed method for ameliorating the effects of inflammation and the referenced method using the same antibodies against GM-CSF. Under the principles of inherency, if a prior art method, in its normal and usual operation, would necessarily perform the method claimed, then the method claimed will be considered to be anticipated by the prior art. When the prior art method is the same as a method described in the specification, it can be assumed the method will inherently perform the claimed process. See MPEP 2112.02.

The reference teachings anticipates the claimed invention.

5. Claims 29-33 stand rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 5,837,460 for the same reasons set forth in the previous Office Action, mailed 05/06/04.

Applicant's arguments, filed 9/25/00 (Paper No. 10), have been fully considered, but have not been found convincing.

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Applicant asserts that : (i) US Patent '460 describes the identification and use of synthetic peptides which mimic GM-CFS and while US Patent '460 indicates that such GM-CFS peptide mimetics may be used as anti-inflammatory agents, this teaching is insufficient to infer that antibodies specific for GM-CFS are useful for ameliorating inflammation.

Contrary to Applicant's assertion, it is the Examiner position that US Patent '460 teaches a method for ameliorating the effects of inflammation, comprising administering antibodies against GM-CSF . Applicant's attention is respectively drawn to column 5 where it is explicitly disclosed that the method of the invention comprises a step of generating antibodies against the biological active protein which is to be mimicked. ( see entire document, Abstract and columns 5 and 9 in particular).

Claims 30 and 33 are included because the claimed functional limitation would be inherent properties of the referenced antibodies against GM-CSF, because the claimed method for ameliorating the effects of inflammation and the referenced method using the same antibodies against GM-CSF. Under the principles of inherency, if a prior art method, in its normal and usual operation, would necessarily perform the method claimed, then the method claimed will be considered to be anticipated by the prior art. When the prior art method is the same as a method described in the specification, it can be assumed the method will inherently perform the claimed process. See MPEP 2112.02.

The reference teaching anticipates the claimed invention.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

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7. Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO 00/09561 or US Patent 5,837,460 each in view of US Patent 5444153 or US Patent 5662609 for the same reasons set forth in the previous Office Action, mailed 05/06/04.

Applicant's arguments, filed 9/25/00 (Paper No. 10), have been fully considered, but have not been found convincing.

Applicant asserts that since WO'561 and US Patent '460 do not anticipate the invention, they should not be used as the primary references and should be removed.

As has been discussed supra, it is the Examiner position that both WO'561 and US Patent '460 do anticipate the invention and thus can be used as the primary references.

The teachings of WO 00/09561 or JP 2000198799 or US Patent 5,837,460 have been discussed, supra.

The claimed invention differs from the reference teaching in that the WO 00/09561, JP 2000198799 and US Patent 5,837,460 do not teach a method for ameliorating the effects of inflammation in a subject comprising administering antibodies against GM-CSF and further administering an agent which antagonizes the effects of u-PA and an agent which antagonizes the effects of other inflammatory mediators.

US Patent '153 teaches a method of treating inflammatory diseases in patients comprising administering specific inhibitors of u-PA ( see entire document, Abstract column 2 and column 5, lines 55-65, and column 6 in particular).

US Patent '609 teaches a method of treating inflammatory diseases in patients comprising administering specific inhibitors of u-PA or inhibitors of agents which inhibits the effects of inflammatory mediators ( see entire document, column 4 and column 6 in particular).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to apply the teaching of US Patent '153 or US Patent '609 to those of WO 00/09561 or US Patent 5,837,460 to obtain a claimed method for ameliorating the effects of inflammation in a subject comprising administering antibodies against GM-CSF and further administering an agent which antagonizes the effects of u-PA and an agent which antagonizes the effects of other inflammatory mediators.

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One of ordinary skill in the art at the time the invention was made would have been motivated to do so, because agent which antagonizes the effects of u-PA and an agent which antagonizes the effects of other inflammatory mediators can be used in the a method of treating inflammatory diseases as taught by US Patent '153 or US Patent '609 and can be combined with a method of treating inflammatory diseases in patients taught by WO 00/09561 or JP 2000198799 or US Patent 5,837,460. "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. . . [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205USPQ 1069, 1072 (CCPA 1980) (see MPEP 2144.06).

The strongest rationale for combining references is a recognition, expressly or impliedly in the prior art or drawn from a convincing line of reasoning based on established scientific principles or legal precedent, that some advantage or expected beneficial result would have been produced by their combination. *In re Semaker*. 217 USPQ 1, 5 - 6 (Fed. Cir. 1983). See MPEP 2144.

From the combined teaching of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

The following new grounds of rejection is necessitated by the amendment filed 11/08/04.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

*The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.*

8. Claims 29-34 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a New Matter rejection.**

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(i) “ an antibody specific for GM-CSF or an antibody specific for M-CSF” claimed in 29, (ii) ... antagonized the effects of M-CSF or GM-CSF on cells”, claimed in claim 29 represent a departure from the specification and the claims as originally filed and applicant has not pointed out where the support come from.

The specification and the claims as originally filed only support (i) “ an antibody against GM-CSF or M-CSF” and (ii) “ ... antagonized the effects of M-CSF or GM-CSF on cells of the monocytes/macrophage lineage ”.

9. No claim is allowed

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

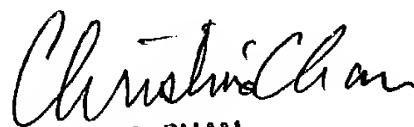
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskiy whose telephone number is 571/ 272-0840. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571/ 272-0841 .

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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November 23, 2004

  
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